



English is not Enough: The Language of Food and Drug Labels

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Executive Summary

English is not Enough: The Language of Food and Drug Labels

By Ryan Arai

Food and drug labels must respond to the needs of the increasing linguistic minority population in the United States. Currently, the FDA only requires that food and drug labels be in English. Due to the growing segment of the population that cannot understand English, the FDA is not able to satisfy its goals of communicating valuable information to consumers through food and drug labels. The majority of the non-English speaking population speaks Spanish, suggesting that the FDA must target this specific linguistic minority with any policy response. The paper poses the question of whether the FDA should require food and drug labels in another language in addition to English.

The paper is divided into five chapters. The first chapter covers the history of the FDA's approach to food and drug labels. The California Supreme Court's decision in *Ramirez v. Plough* is analyzed in the second chapter.¹ The third chapter examines the Canadian model of bilingual French/English food and drug labels. Six possible policy options are covered in chapter four. Chapter five, the policy recommendation, concludes that the FDA should ask for comment on a proposal for bilingual English/Spanish warnings and directions on over-the-counter drugs combined with a foreign language patient package insert program for prescription drugs.

The paper concludes that a mandate of bilingual over-the-counter drug labels combined with a foreign language patient package insert program is an appropriate and proportionate FDA response to the increasing needs of linguistic minorities.

¹*Ramirez v. Plough*, 863 P.2d 167 (Cal. 1993).

English is not Enough: The Language of Food and Drug Labels

By Ryan Arai²

Introduction

Tropicana Products, Bradenton, Florida, announced... it is launching a line of Dole chilled orange juices with bilingual English/Spanish packaging and that all Dole juice packaging will go bilingual over the next year.

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Multilingual labels for food and drug labels have become a critical issue for corporations and the Food and Drug Administration (FDA), as indicated by Tropicana Products' announcement. In the United States, food and drug labels are only required to be in one language: English.⁴ Given that English is the sole official language of the United States, this policy is not surprising. Nevertheless, shifting population patterns, past FDA policies, and the informational goals of food and drug labels indicate that bilingual English/Spanish labels may be necessary. A case can be made for labels in languages other than Spanish or English, as well. Although corporations like Tropicana Products are voluntarily implementing a policy of bilingual labels, the FDA can institute regulations to requiring multilingual labels on all food and drug products. Should the FDA implement regulations requiring food and/or drug labels in a language in addition to English? In order

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⁴*See* Food: Prominence of Required Statements, 21 C.F.R. 101.15(c)(1) (2002) (stating All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language); *See also* Drugs: Prominence of Required Label Statements, 21 C.F.R. 201.15(c)(1) (2002) (stating All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language).

to answer this question, the goals of food and drug labels must be identified and the linguistic population patterns of the United States must be analyzed.

Food and drug labels provide valuable consumer information deemed necessary by the FDA. Regulation of food labels in the United States serve four main purposes. First, the label gives the consumer nutritional information about the product, allowing the consumer to make decisions based upon dietary concerns. Second, the ingredient list on the label allows the consumer to avoid purchasing products with unwanted ingredients, based on allergies, for example.⁵ Food allergies are a serious health risk that may affect 8 percent of children and 2 percent of adults.⁶ Third, regulations prevent labels from carrying misleading information. Fourth, warnings on food labels alert consumers to possible risks caused by the product.⁷ With the exception of the third purpose, these FDA labeling objectives are not met for consumers who cannot read English.

Drug labels serve two FDA goals: providing consumers with adequate directions for use and alerting consumers to possible health risks posed by the products.⁸ Neither of these objectives is satisfied for over-the-counter drug consumers who have difficulty reading English. For prescription drugs, the warning of possible health risks must be conveyed from the drug manufacturer to the prescribing physician, who acts as a learned intermediary between the drug manufacturer and the patient.⁹ Warnings on drug labels must include possible side effects and adverse reactions.¹⁰ Drug labels are often more important than food labels

⁵See Peter Barton Hutt & Richard A. Merrill, *FOOD AND DRUG LAW: CASES AND MATERIALS*, 75 (The Foundation Press, Inc., 2d ed. 1991) (stating [I]n recent years, attention has focused on the consumer's ability to identify [sic] and avoid specific ingredients).

⁶*Id.* at 83 (citing Metcalfe, *Diseases of Food Hypersensitivity*, 321 N.E.J.M. 255 (July 27, 1989)).

⁷See Food labeling Warning, Notice, and Safe Handling Statements, 21 C.F.R. 101.17 (2002) (stating, for example, [S]elf-pressurized containers with halocarbon or hydrocarbon propellants... shall bear the following warning: Warning – Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal).

⁸See Peter Barton Hutt & Richard A. Merrill, *FOOD AND DRUG LAW: CASES AND MATERIALS*, 401 (The Foundation Press, Inc., 2d ed. 1991) (citing *Alberty Foods Prods. V. United States*, 194 F.2d 463 (9th Cir. 1952) stating [I]n order for the labeling of a drug to bear 'adequate directions for use'... it must, among other things, state the purposes and conditions for which the drug was intended and sufficient information to enable a layman to intelligently and safely attempt self medication); See, e.g., *Misbranded drugs and devices* 21 U.S.C. 352 (2002) (stating [A] drug or device shall be deemed to be misbranded... [U]nless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application).

⁹See Hutt & Merrill, *supra* note 4, at 426 (citing *MacDonald v. Ortho Pharmaceutical*, 475 N.E.2d 65 (Mass. 1985)).

¹⁰*Cf. id.* at 434 (stating [A]n adequate warning of possible danger must appear in all such labeling. Without such a warning, a product is misbranded).

because the possible dangers of side effects or misuse are more severe.¹¹ The goals of providing warnings and adequate directions for use are not satisfied for prescription drug consumers who have difficulty reading English.

Shifting population patterns indicate that less and less people in the United States can understand food and drug labels that are written in English. Before 1980, the United States Census did not inquire about citizens' ability to speak English nor which language is spoken at home. United States Census statistics regarding language only cover the 1980 and 1990 census. The language ability statistics from the 2000 census are not yet available. The percentage of the population that speaks English not well or not at all at home has increased since 1980. In 1980, 2.02 percent of the United States population over the age of 5 spoke English not well or not at all in the home.¹² By 1990, the percentage of people over the age of 5 who spoke English not well or not at all in the home had increased to 2.90 percent.¹³ Thus, the percentage of people who spoke English not well or not at all at home increased by 70 percent between 1980 and 1990.¹⁴ In 1990, approximately 6,672, 000 people over the age of 5 in the United States spoke English not well or not at all.¹⁵ The FDA goals of food and drug labeling cannot be satisfied for over 6 million people because they cannot read English labels.

The majority of the United States population that speaks English not well speaks Spanish. Like the percentage of people who cannot speak English well, the percentage Spanish-speakers who speak English not well increased between 1980 and 1990. In 1980, approximately 64 percent of the persons over the age of 5 who spoke English not well spoke Spanish.¹⁶ By 1990, that percentage had jumped to approximately 67

¹¹ *Cf. id.*, at 27 (citing *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, (7th Cir. 1983), stating To qualify as a drug under Section 321(g)(1)(C), the articles must not only be articles 'other than food,' but must also be 'intended to affect the structure or any function of the body of man or other animals').

¹²1 BUREAU OF THE CENSUS, 1980 CENSUS OF POPULATION, Chapter D, Part 1, Section A, Table 258 (1984).

¹³1990 United States Census: Detailed Language Spoken at Home and Ability to Speak English for Persons 5 Years and Over, available at <http://www.census.gov/population/socdemo/language/table5.txt> (last visited March 27, 2002).

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶1 BUREAU OF THE CENSUS, 1980 CENSUS OF POPULATION, Chapter D, Part 1, Section A, Table 258 (1984).

percent. During those 10 years, the number of Spanish speakers who spoke English not well increased from approximately 2,636,000 to 4,501,000.¹⁷ The rapid growth of the Latino population in the United States is predicted to continue.¹⁸ The proportion of Latinos in the United States population is projected to rise from 9.0 percent in 1990 to 22.5 percent in 2050.¹⁹ As the number of Latinos rises, the number of Spanish speakers promises to increase as well.

A large percentage of the Spanish speaking population is concentrated in a few states. In 1990, approximately 70 percent of the Spanish speaking persons over the age of 5 in the United States resided in California, Florida, New York, and Texas.²⁰ The percentage of Spanish speaking persons over the age of 5 in these four states is significantly higher than the national average of 7.5 percent.²¹ The 1990 percentages of the state population over the age of 5 that spoke Spanish at home are as follows:

Table 1.1: Percentage of State Population 5 Years and Over Speaking Spanish at Home in 1990²²:

California:	20.01 percent (5,478,712 persons)
Florida:	11.97 percent (1,447,747 persons)
New York:	11.04 percent (1,848,825 persons)
Texas:	22.06 percent (3,443,106 persons)

The Spanish speaking population in these states increased dramatically between 1980 and 1990. In California, the number of persons 5 years and over speaking Spanish at home grew by approximately 2,346,000 from 1980 to 1990, a 74.9 percent increase.²³ Florida's population 5 years and over speaking Spanish at home rose by approximately 661,503 between 1980 and 1990, a growth of 84.1 percent.²⁴ The number of persons

¹⁷ Compare *id.* with 1990 United States Census: Detailed Language Spoken at Home and Ability to Speak English for Persons 5 Years and Over, available at <http://www.census.gov/population/socdemo/language/table5.txt> (last visited March 27, 2002).

¹⁸ Drucilla Cornell & William W. Bratton, *Deadweight Costs and Intrinsic Wrongs of Nativism: Economics, Freedom, and Legal Suppression of Spanish*, 84 CORNELL L. REV. 595, 608 (March 1999) (stating inflows of Latinos/as... which began in the 1950s and 1960s, promise to continue indefinitely and without abatement).

¹⁹ *Id.*, at 609 (citing Hispanic Americans: A Statistical Sourcebook 11 (Louise L. Horner ed., 1996)).

²⁰ 1990 United States Census: Language Use and English Ability, Persons 5 Years and Over, by State, available at <http://www.census.gov/population/socdemo/language/table1.txt> (last visited March 27, 2002).

²¹ *Id.*

²³ Compare *id.* with 1 BUREAU OF THE CENSUS, 1980 CENSUS OF POPULATION, Chapter C, Part 6, Table 63 (1983).

²⁴ Compare 1990 United States Census: Language Use and English Ability, Persons 5 Years and Over, by State, available at <http://www.census.gov/population/socdemo/language/table1.txt> (last visited March 27, 2002) with 1 BUREAU OF THE CENSUS, 1980 CENSUS OF POPULATION, Chapter C, Part 11, Section 1, Table 63 (1983).

5 years and over speaking Spanish at home in Texas increased by approximately 959,000 between 1980 and 1990, a 38.6 percent jump.²⁵ Not only is the Spanish speaking population in the United States primarily concentrated within a few states; the Spanish speaking population is growing rapidly within these few states. The size of the Spanish speaking population has not gone unnoticed; food and drug advertisers recognize the purchasing power of this segment of the population. The Latino purchasing power in the United States exceeds \$492 billion.²⁶ One expert estimates that prescription and other-the-counter drug advertising in the Latino media totaled \$40 million in 1998 and that number could grow as fast as Spanish-language media outlets seek to harness the increasing size and power of the U.S. Hispanic market.²⁷ Another expert notes, For prescription and over-the-counter drug makers, there is a big time opportunity (to reach the Latino population through advertising) because there is a big time need to be filled.²⁸ Moreover, the appeal of Latino consumers is not limited to the drug industry. As indicated by the bilingual labels on Dole juice, food companies are focusing advertising efforts on Spanish speaking consumers. For example, Gatorade just launched a Spanish language advertising campaign for its new Extremo drinks.²⁹ Mary Dillon, Vice President - Product Offerings for Gatorade, said, [L]atinos constitute a large segment of the population in some of our strongest markets, confirming the influence of Latino consumers.³⁰ Advertisers are catering to Spanish speaking consumers because of the size of the Latino population in the United States; however, the labels on the products rarely provide information in Spanish because the FDA only requires that labels be in English.

²⁵ Compare 1990 United States Census: Language Use and English Ability, Persons 5 Years and Over, by State, available at <http://www.census.gov/population/socdemo/language/table1.txt> (last visited March 27, 2002) with 1 BUREAU OF THE CENSUS, 1980 CENSUS OF POPULATION, Chapter C, Part 45, Table 63 (1983).

²⁶ Derek Reveron, *Merger Fever: Hispanic Ad Agencies Increasingly Make Tempting Takeover Targets for International Conglomerates*, HISPANIC BUSINESS, Oct. 2001, at 42.

²⁷ Mary Wagner, *Rx Solution: Hispanic Households Most Attractive, Attentive Target with Proper In-language Approach*, ADVERTISING AGE, Aug. 30, 1999, at S16 (quoting Ingrid Otero-Smart, Executive Vice President - Client Research at Mendoza, Dillon Asociados, Newport Beach, California).

²⁸ *Id.* (quoting Andrew Erlich, president of research firm Erlich Transcultural Consultants).

²⁹ Kate MacArthur, *Gatorade Spin-off Targets Hispanics: Dieste Creates Spanish-Language Ads for New Extremo Drinks*, Adage.com, available at <http://www.adage.com/news.cms?newsId=34277> (March 21, 2002).

³⁰ *Id.*

This paper explores whether the FDA should require food and drug labels to appear in another language in addition to English. The issue is broken down into five chapters. The first chapter covers the history of the FDA's approach to food and drug labels. This chapter includes the FDA's exceptions to the English-only label rule and the FDA's brief experiment with foreign language patient package inserts for prescription drugs. In the second chapter, the California Supreme Court's decision in *Ramirez v. Plough* will be analyzed.³¹ This case concerned whether an over-the-counter drug manufacturer is liable to a Spanish speaking consumer for failing to provide warnings in Spanish, resulting in the severe retardation of the consumer's son.³² The third chapter examines the Canadian model of bilingual food and drug labels. In Canada, food and drug labels provide information in both French and English. Possible policy options are covered in chapter four. The policy options range from low impact solutions like expanded use of warning symbols on labels to high impact solutions like state regulation of food and drug labels. Chapter five, the policy recommendation, concludes that the FDA should ask for comment on a proposal for bilingual English/Spanish warnings and directions on over-the-counter drugs combined with a foreign language patient package insert program for prescription drugs. These drug regulation recommendations solve the communication deficiency for the most vulnerable Spanish speaking consumers and could pave the way for further FDA label language changes in the future.

³¹*Ramirez v. Plough*, 863 P.2d 167 (Cal. 1993).

³²*See id.*

Chapter One: History of FDA's Approach to Labels

Traditionally, the FDA approach to food and drug labels has been a policy of English only, however, particular instances show that the FDA is not averse to the concept of labels in other languages. This chapter will cover the FDA's English only rule as well as circumstances when the FDA has allowed labels in languages other than English. First, the chapter analyzes the rules and rationale of the FDA's English only policy. Second, the statutory exceptions of the English only rule are examined. Third, the chapter includes the brief history of foreign language patient package inserts for prescription drugs. The chapter concludes with concern that despite the increasingly large foreign language speaking population, the FDA has not adequately explored the need for multilingual labels since the early 1980s.

Section 1: Rules and Rationale for FDA English-only policy

The FDA only requires food and drug labels to be in English (the English only policy). Food labels must include the following information in English: the name of the food, the manufacturer's name and place of business, a statement of ingredients, net quantity of contents and nutrient content.³³ The statute provides that [A]ll words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language.³⁴ Identical wording, conveying the English only policy, appears in the drug labeling statute.³⁵ These two statutes do not require food or drug labels to use any language in addition to English.³⁶

The rationales for the FDA's English only labeling policy include concerns about manufacturing costs, translation issues, label space limitations, and effectiveness of label warnings. The FDA is deterred from a

³³See Hutt and Merrill, *supra* note 4, at 60-61.

³⁴Food: Prominence of Required Statements, 21 C.F.R. 101.15(c)(1) (2002).

³⁵See Drugs; Prominence of Required Label Statements, 21 C.F.R. 201.15(c)(1) (2002) (stating [A]ll words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language).

³⁶*But cf. id.* (allowing, but not requiring, Spanish to be substituted for English in the case of articles distributed solely in the Commonwealth of Puerto Rico).

requirement of multilingual labels because such a policy would raise manufacturing costs for food and drug companies.³⁷ Nevertheless, under a theory of language rights, a concept currently in the academic discourse, economic concerns do not justify language discrimination.³⁸ Moreover, until the manufacturers assume the economic costs of linguistic accommodation, non-English speakers are bearing these costs for the economy.³⁹

Accurate translation of FDA warnings and required wording is a primary concern about labels provided in foreign languages.⁴⁰ For drugs distributed only in Puerto Rico, the FDA provides standardized English-to-Spanish translations for required prescription drug warnings on labels.⁴¹ However, the FDA already provides translations for some food and drug labels, and further translations could be provided to food and drug manufacturers at minimal cost.⁴²

³⁷ Cf. *Ramirez v. Plough*, 863 P.2d 167, 175 (Cal. 1993) (stating the United States is too heterogenous to enable manufacturers, at reasonable cost and with reasonable simplicity to provide multilingual patient package inserts).

³⁸ See Drucilla Cornell & William W. Bratton, *Deadweight Costs and Intrinsic Wrongs of Nativism: Economics, Freedom, and Legal Suppression of Spanish*, 84 CORNELL L. REV. 595, 599-600 (March 1999) (stating two factors—cost and volition—strictly delimit the permissible scope of non-English speakers’ claims for equality of treatment. As to cost, there is a broad zone of economically justified discrimination against non-English speakers); See Christina Rodriguez, *Accommodating Linguistic Difference: Toward a Comprehensive Theory of Language Rights in the United States*, 36 HARV.C.R.-C.L. L. REV. 133, 135 (Winter 2001) (stating the concept of ‘language rights’ has meaning in an American context and is not just reserved for officially multilingual societies such as Canada and Spain).

³⁹ See Drucilla Cornell & William W. Bratton, *Deadweight Costs and Intrinsic Wrongs of Nativism: Economics, Freedom, and Legal Suppression of Spanish*, 84 CORNELL L. REV. 595, 608 (March 1999) (stating multiple languages do result in added costs for a given economy. But... these costs fall most heavily on minority language speakers themselves).

⁴⁰ See Drugs; Spanish-language version of certain required statements, 21 C.F.R. 201.16 (revised April 1, 2001) (stating [A]n increasing number of medication restricted to prescription use only are being labeled solely in Spanish for distribution in the Commonwealth of Puerto Rico where Spanish is the predominant language... Two required warnings, the wording of which is fixed by law in the English language, are presently being translated in various ways, from literal translation to loose interpretation. The statutory nature of these two statements requires that the translation must convey the meaning properly, in order to avoid confusion and dilution of the purposes of the warnings).

⁴¹ See, e.g., *Id.* (stating [T]he Commissioner of Food and Drugs hereby adopts the following Spanish language versions as the accepted equivalents of the English wording of the following: (a) Section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act requires the statement ‘Caution: Federal law prohibits dispensing without prescription.’ The Spanish version of this shall be: ‘Precaucion: La ley Federal prohíbe su despacho sin prescripcion facultativa.’ (b) Section 502(d) of the Federal Food, Drug, and Cosmetic Act requires the statement ‘Warning—May be habit forming’ on habit-forming drugs. The Spanish version of this shall be: ‘Aviso—Puede formar habito o vicio’).

⁴² See, e.g., Spanish-language version of required warning, 21 C.F.R. 290.6 (Revised April 1, 2001) (stating the law requires the following warning on the label of certain drugs when dispensed to or for a patient: ‘Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.’ The Spanish version of this is: ‘Precaucion: La ley Federal prohíbe el transferir de esta droga a otra persona que no sea el paciente para quien fue receta’).

Label space considerations discourage the FDA from requiring multilingual labels on food and drugs. The law provides that multilingual labels must provide all the required elements of the label in each language.⁴³ For example, a bilingual Spanish-English food label must include the name of the food, manufacturer's name and place of business, statement of ingredients, net quantity of contents and nutrient content in both languages. Thus, multilingual labels consume more label space with statutorily required elements in more than one language, leaving less space for product advertisement and promotion. In spite of these concerns, products like Dole Juice voluntarily use bilingual labels as a method for appealing to non-English speaking populations.⁴⁴ Thus, products can potentially increase their consumer appeal by using multilingual labels, despite having less label space for product advertisement and promotion.

Increasing the information required on food and drug labels can detract from the effectiveness of warnings on these labels. One cost of an additional warning on a label is that a new warning dilutes the effectiveness of the old warning.⁴⁵ However, this desensitizing cost is avoided with multilingual labels because an English speaking consumer will not be able to read the warning written in another language.⁴⁶

The FDA codified a policy of only requiring English language on food and drug labels. Nevertheless, the rationale for this English-only policy can be called into question.

Section 2: Exceptions to the English-Only Policy

The FDA carves out two exceptions for the English-only policy for food and drug labels. First, products distributed solely in a United States territory where the primary language is other than English, like Puerto Rico, can have labels printed in the primary language of the territory.⁴⁷ The wording of the statute states

⁴³ See Food: Prominence of Required Statements, 21 C.F.R. 101.15(c)(2) (2002); See Drugs: Prominence of Required Label Statements, 21 C.F.R. 201.15(c)(2) (2002).

⁴⁴ See Stephanie Thompson, *All Dole Juice to go Bilingual: English-Spanish Text to Become the Norm*, Ad Age, available at www.adage.com (April 2, 2002).

⁴⁵ Roger Enriquez, *I'm Warning You: Over-the-Counter Drug Manufacturers That Advertise in Spanish Should Warn in Spanish*, 4 J. GENDER RACE & JUST. 353, 364 (Spring 2001) (citing *Carlin v. Superior Ct.*, 920 P.2d 1347, 1360 (Cal. 1996)).

⁴⁶ See *id.*

⁴⁷ See Drugs: Prominence of Required Label Statements, 21 C.F.R. 201.15(c)(1) (2002); See Food: Prominence of Required Statements, 21 C.F.R. 101.15(c)(1) (2002).

in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.⁴⁸ Note that the statute does not require Spanish labels for products distributed in Puerto Rico, it merely allows products that are only distributed in Puerto Rico not to have English labels. Thus, even though the native and primary language in Puerto Rico is Spanish, the FDA does not require Spanish labels for food and drugs distributed in Puerto Rico. Nevertheless, the fact that the FDA carves out an exception for territories the size of Puerto Rico provides evidence that the FDA is concerned about conveying information and warnings to concentrated non-English speaking populations. Similar concentrated non-English speaking populations exist within the continental United States.⁴⁹ Nevertheless, these communities within the continental United States are not covered by the statutory exception.

Second, a label that contains any representation in a foreign language must include all of the information required by FDA in that foreign language.⁵⁰ The statute states [I]f the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.⁵¹ The statute also provides [I]f any article of labeling (other than a label) contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on such article of labeling.⁵² Thus, products like Dole Juice, which use bilingual labeling, must provide all of the label information required by the FDA in both Spanish and English. This provision ensures

⁴⁸Drugs; Prominence of Required Label Statements, 21 C.F.R. 201.15(c)(1) (2002); Food: Prominence of Required Statements, 21 C.F.R. 101.15(c)(1) (2002).

⁴⁹*Cf.* Drucilla Cornell & William W. Bratton, *Deadweight Costs and Intrinsic Wrongs of Nativism: Economics, Freedom, and Legal Suppression of Spanish*, 84 CORNELL L. REV. 595, 608 (March 1999) (citing Douglas S. Massey, *The New Immigration and Ethnicity in the United States*, 21 POPULATION & DEV. REV. 631, at 647 tbl. 2 (1995) stating [L]atinos/as have gravitated to a small number of enclave communities rather than dispersing across the continent. . . a recent study found that today's top five receiving states take in 78.2% of arrivals and today's top five receiving metropolitan areas take in 47.9% of arrivals).

⁵⁰*See* Drugs; Prominence of Required Label Statements, 21 C.F.R. 201.15(c)(2) (2002); *See* Food: Prominence of Required Statements, 21 C.F.R. 101.15(c)(2) (2002).

⁵¹Drugs; Prominence of Required Label Statements, 21 C.F.R. 201.15(c)(2) (2002); Food: Prominence of Required Statements, 21 C.F.R. 101.15(c)(2) (2002).

⁵²Drugs; Prominence of Required Label Statements, 21 C.F.R. 201.15(c)(3) (2002); Food: Prominence of Required Statements, 21 C.F.R. 101.15(c)(3) (2002).

that products appealing to consumers with foreign language on the packaging must provide FDA required information, such as directions for use and warning on over-the-counter drugs, in the foreign language used on the packaging. The provision ensures that manufacturers cannot appeal to a foreign language speaking consumer with on-package advertising, without providing the necessary information and warnings in that foreign language. Nevertheless, products like Gatorade, which use Spanish language advertisements through the media and not directly on the packaging, circumvent this exception. The FDA's rationale for this exception is to ensure that products directly appealing to foreign language populations, by using that foreign language in promotion, must bear adequate warnings and information in that foreign language. By this reasoning, the rationale for labeling requirements is satisfied, namely to communicate important information to the consumer. Nevertheless, the FDA cannot accomplish this goal until representations in all advertisements, including television, radio, and periodical advertisements, are included in this exception, not just representations on packaging.

Section 3: The FDA Experience with Patient Package Inserts

The FDA's most extensive experience with foreign language labeling involved the patient package insert requirement that existed in the early 1980s. In September of 1980, the FDA implemented a patient package insert mandate for prescription drugs. The requirement was derived from informational inserts that were required to be distributed with prescription oral contraceptives during the 1970s. The patient package insert, which was required to physically accompany prescription drugs, contained:

both a summary of information about the product and more detailed information that identifies the product and the person responsible for the labeling, the proper uses of the product, circumstances under which it should not be used, serious adverse reactions, precautions the patient should take when using the product, information about side effects, and other general information about the proper uses of prescription drug products.⁵³

Patient package inserts were meant to supplement the drug information provided to a patient by the pre-

scribing physician.

The patient package insert mandate was implemented for four main reasons. First, inserts promote the safe and effective use of prescription drug products in the same manner as an over-the-counter drug label.⁵⁴ Second, inserts provide patients with the benefits, risks, and directions for use of products, information that previously was only available to the prescribing physician.⁵⁵ Third, the FDA believed that inserts would both reduce potential liability for prescription drug manufacturers and reduce the overall number of malpractice actions for physicians.⁵⁶

The FDA recognized that all of these rationales justified making foreign language inserts available to non-English speaking patients.⁵⁷ The FDA encouraged that manufacturers provide non-English language patient package inserts where appropriate.⁵⁸ An exception was made for the sizable Spanish speaking population; patient package inserts were required to be available in Spanish.⁵⁹ The FDA noted that the sizable Spanish speaking minority in this country should have access to patient package inserts in its primary language.⁶⁰

The statute stated:

The regulations require, however, that manufacturers prepare patient package inserts written in Spanish so that they can provide adequate supplies in Spanish upon request to distributors and dispensers to whom they have shipped the drug. The agency encourages practitioners and dispensers to obtain and provide to their Spanish speaking patients Spanish language patient package inserts.⁶¹

The FDA believed that a Spanish language patient package insert requirement would not unnecessarily

⁵⁴*Id.*

⁵⁵*Id.*

⁵⁶*Id.*

⁵⁷Prescription Drug Products: Patient Package Insert Requirements, 45 Fed. Reg. 60754 (Sept. 12, 1980) (stating that providing non-English language patient package inserts is encouraged where appropriate. . . the provision in the regulations is intended to permit dispensers to provide alternative patient package inserts in languages other than English).

⁵⁸*Id.*

⁵⁹*Id.*

⁶⁰*Id.*, at note 49.

burden manufacturers.⁶² Even though the Spanish patient package inserts were required to be made available by manufacturers, dispensing of the Spanish inserts by pharmacists was optional.⁶³

The patient package insert requirement did not last for long; the requirement was revoked in 1982.⁶⁴ The program was revoked in total, both English and Spanish patient package inserts, because of cost concerns and conflicts about the structure of the system.⁶⁵ Another rationale for discontinuing the patient package insert program was that physicians and drug manufacturers were providing more effective new initiatives in patient information.⁶⁶ Despite the fact that the program was short-lived, the patient package insert requirement represents the most comprehensive attempt of the FDA to provide labels in a language other than English. The patient package insert program provides valuable lessons for any multilingual labeling agenda. First, the program was cost-effective and efficient because the inserts were available upon request by a pharmacist, presumably to satisfy the request of a patient. Thus, pharmacists in Latino neighborhoods could plan ahead and readily provide their customers with Spanish language patient package inserts. However, this method was underinclusive because it was unlikely to serve Spanish speaking customers outside of Latino neighborhoods unless the customers knew to request Spanish language patient package inserts. Second, the FDA recognized the difficulty that manufacturers encountered in accurately translating the insert information from English to Spanish. The FDA noted many drug manufacturers will find it difficult to obtain Spanish translations of FDA's English language guideline patient package inserts that they can rely on to comply

⁶²*Id.*, at note 49.

⁶³*Id.*, at note 49 (stating the agency has revised the regulations to require that manufacturers prepare an adequate amount of patient package inserts in Spanish so that they can be supplied, upon request, by the person, for example, the local pharmacist, to whom the drugs are shipped...[D]ispensing of Spanish patient package insert, like other non-English language patient package inserts, is optional).

⁶⁴Prescription Drug Products: Revocation of Patient Package Insert Requirements, 47 Fed. Reg. 39147 (Sept. 7, 1982).

⁶⁵*Id.* (stating the program was revoked because the limited value of providing patient information only at the time of dispensing, the cost of the mandatory program, the strong disagreement about the design and value of the program on the part of the health professionals who would have to implement it, and the need for Federal regulations to be both necessary and cost effective).

⁶⁶*Id.* (stating since the promulgation of the pilot program, the private sector had provided new initiatives in patient information and was currently developing others...the agency stressed that cooperation with the private sector would encourage experimentation with diverse systems for delivering patient information, thereby promoting innovation in delivery systems).

with the agency's regulations.⁶⁷ Standardized translations, provided by the FDA, solved this problem.⁶⁸ By publishing standardized Spanish translations, the FDA shifted the translation costs away from the drug manufacturers. The patient package insert program provides guidance for implementation of future non-English labeling provisions.

The patient package insert program demonstrated that the FDA recognized the desirability of Spanish language food and drug labels as early as 1980. The Spanish speaking population has grown remarkably since 1980; however, the FDA has not made another significant attempt to require food or drug labels in a language other than English since the demise of the patient package insert program. Given the modern population trend coupled with the FDA's rationale for Spanish patient package inserts, the FDA must consider the feasibility of implementing another Spanish language label requirement.

⁶⁷Prescription Drugs: Final Guideline Patient Package Inserts for Ampicillin and Phenytoin, 46 Fed. Reg. 160 (Jan. 2, 1981).

⁶⁸*See id.* (stating FDA will prepare and make available Spanish language guideline patient package inserts).

Chapter 2: Ramirez v. Plough

In 1993, the Supreme Court of California decided *Ramirez v. Plough* (*Ramirez*), finding that a drug manufacturer cannot be liable for failing to provide over-the-counter drug label warnings in Spanish.⁶⁹ *Ramirez* is the only case asking for over-the-counter drug labels to be required in a foreign language that has made it as high as the state supreme court. First, this chapter will analyze the court's decision in *Ramirez*. Second, the implications of *Ramirez* for foreign language labels on food and drugs will be covered. The chapter concludes that *Ramirez* shifted the burden of deciding whether labels should be required in foreign languages from the judicial system to the government, namely to the FDA.

Section 1: Case Analysis

Ramirez involved a tort action alleging negligence, products liability, and fraud on the part of Plough, Inc. (defendant) for manufacturing St. Joseph Aspirin for Children (SJAC) without warnings in Spanish language.⁷⁰ In 1986, Jorge Ramirez (plaintiff) contracted Reye's syndrome when he was less than four months old after his Spanish speaking mother gave him SJAC to alleviate cold symptoms.⁷¹ The plaintiff's mother could not read the English warnings on the SJAC package, which stated:

Warning: Reye Syndrome is a rare but serious disease which can follow flu or chicken pox in children and teenagers. While the cause of Reye Syndrome is unknown, some reports claim aspirin may increase the risk of developing this disease. Consult doctor before use in children or teenagers with flu or chicken pox. The symptoms of Reye syndrome can include persistent vomiting sleepiness and lethargy, violent headaches, unusual behavior, including disorientation, combativeness, and delirium. If any of these symptoms occur, especially following chicken pox or flu, call your doctor immediately, even if your child has not taken any medication. Reye Syndrome is serious, so early detection and treatment is vital.⁷²

The plaintiff's mother, who was from Mexico, had traditionally used aspirin as a remedy for headaches.⁷³

⁶⁹*Ramirez v. Plough*, 863 P.2d 167 (Cal. 1993).

⁷⁰*Id.*, at 168.

⁷¹*Id.*, at 169.

⁷³*Id.*, at 170.

After continued treatment with SJAC, the plaintiff developed Reye's syndrome.⁷⁴ The disease resulted in severe neurological damage, including cortical blindness, spastic quadriplegia, and mental retardation.⁷⁵ The defendant promoted SJAC with Spanish advertisements in Los Angeles and New York.⁷⁶ However, the plaintiff's mother did not see or hear any of these advertisements.⁷⁷ The severely retarded plaintiff, through his mother as guardian ad litem, sued Plough, Inc. for tort liability resulting from failure to adequately warn consumers about Reye's syndrome.⁷⁸

Leading up to *Ramirez*, the defendant moved for summary judgment claiming that it did not have a duty to use Spanish language warnings on the SJAC label.⁷⁹ The court granted the summary judgment, concluding that there was no duty to warn in a foreign language.⁸⁰ The Court of Appeal reversed the district court's decision, holding that the issue of the case was the adequacy of the warning. The court concluded that the reasonableness of the defendant's choice not to label SJAC with a Spanish warning, despite the fact that the defendant knew that SJAC was being used by Hispanics and that the defendant advertised in Spanish, was a triable issue of fact.⁸¹ The California Supreme Court (the Court) granted review and held in favor of the defendant, finding that a drug manufacturer may not be liable in tort for failing to label a nonprescription drug with warnings in a language other than English.⁸²

According to the Court, the issue of the case was whether defendant's duty to warn required it to provide label or package warnings in Spanish.⁸³ Curiously, the Court rejected the reasonably prudent person under like circumstances standard of care that was recommended by the Court of Appeals.⁸⁴ Instead, the Court

⁷⁴ *Id.*, at 169.

⁷⁵ *Id.*

⁷⁶ *Id.*, at 170.

⁷⁷ *Id.*, at 177.

⁷⁸ *Id.*, at 170.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*, at 170-71.

⁸² *Id.*, at 168.

⁸³ *Id.*, at 171.

⁸⁴ *Id.*

allowed the defense of statutory compliance for the standard of care argument.⁸⁵ The Court conceded that courts rarely allow the defense of statutory compliance.⁸⁶ Nevertheless, the Court allowed the defense because the language of over-the-counter drug labels is governed by a dense layer of state and federal statutes and regulations that control virtually all aspects of the marketing of its products.⁸⁷

The Court employed a survey of federal and state laws to support its argument that foreign language labeling is closely regulated area to be controlled by the government, not the judicial system.⁸⁸ Unlike the Court of Appeals, the Court refused to consider statutes concerning foreign-language warnings for products other than over-the-counter drugs and regulations of the scope of an employer's duty to warn non-English-speaking employees of workplace hazards.⁸⁹ As a result, the only federal statutes that the court analyzed were FDA labeling rules.⁹⁰ The Court reviewed the FDA drug labeling requirements, 21 C.F.R. 201; especially the language requirements for drug labels, 21 C.F.R. 201.15(c).⁹¹ By the Court's interpretation, the statute only requires English language on drug labels. However, the Court did note the ambiguity of the term representation in §201.15(c)(3).⁹² This section of the statute states that [I]f the labeling contains any *representation* (italics added) in a foreign language, all words, statements and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.⁹³

The Court intimated that representation could be read to exclude an abbreviated warning, such as a Spanish

⁸⁵*Id.*, at 172; *But Cf. Id.*, at 172 (citing Rest. 2d Torts, §288C, com. A, p. 40, stating the standard defined is normally a minimum standard, applicable to the ordinary situations contemplated by the legislature. This legislative or administrative minimum does not prevent a finding that a reasonable [person] would have taken additional precautions where the situation is such as to call for them).

⁸⁶*Id.*, at 172 (stating [C]ourts have generally not looked with favor upon the use of statutory compliance as a defense to tort liability).

⁸⁷*Id.*

⁸⁸*See id.*, at 173.

⁸⁹*See id.*, at 171 (stating the Court of Appeal cited and relied upon cases involving the labeling of pesticides and solvents and cases imposing requirements on employers to communicate warnings effectively to non-English-speaking employees but refusing to consider these cases).

⁹⁰*See id.*, at 173-74.

⁹¹*See id.*

⁹²*See id.*, at 174 (stating [I]t is unclear what constitutes a 'representation' within the meaning of this regulation. If the term includes only factual representations about the uses or effectiveness of the product, then some abbreviated warnings (such as, 'If you do not read English, ask someone to translate this label for you before using this product') in a foreign language might not violate the regulation).

⁹³Drugs: Prominence of Required Label Statements, 21 C.F.R. 201.15(c)(3) (2002).

warning to have someone translate the label if the consumer cannot read English.⁹⁴ By this reading, such a warning would not require the manufacturer to supply Spanish versions of the drug's directions for use and warnings on the label. Extending this argument, such an abbreviated warning might be a reasonable effort for a drug manufacturer that advertises in Spanish. One critic contends that labeling as used in §201.15(c)(3) should be read to include advertising.⁹⁵ Nevertheless, the Court does not contemplate this interpretation of §201.15(c)(3). The Court concluded that federal law is sufficiently delineated to cover language use on drug labels, so it is reasonable to infer that the (FDA) has deliberately chosen not to require that manufacturers also include warnings in foreign languages.⁹⁶

The Court's analysis of California state law is more expansive than its survey of Federal regulations. California law does not explicitly require drug label warnings in any language other than English.⁹⁷ Unlike the Court's analysis in federal laws, the survey of California regulations is not limited to labeling standards. The Court considered government agencies' duty to provide certain documents in foreign languages and specific duties of parties to private commercial transactions to make information available in languages other than English. Despite language use requirements in these areas, the Court found that the state legislature has sufficiently delineated language use regulations such that the Court can conclude that the legislature consciously chose not require drug labels in foreign languages.⁹⁸

The Court also concluded that a statutory interpretation of the standard of care was the most practical option.⁹⁹ The court offered, and then rejected, two other standard of care options. First, the Court considered

⁹⁴See *Ramirez v. Plough*, 863 P.2d 167, 174 (Cal. 1993).

⁹⁵See Roger Enriquez, *I'm Warning You: Over-the-Counter Drug Manufacturers That Advertise in Spanish Should Warn in Spanish*, 4 J. GENDER RACE & JUST. 353, 359-60 (Spring 2001) (stating '[T]he term "labeling" is defined as including all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' The courts have read the labeling definition very broadly. In *Kordel v. United States* (335 U.S. 345 (1948)), the Supreme Court held that the labeling definition 'clearly embraces advertising.'... Therefore, any written, printed, or graphic material used in the sale of a drug to supplement or explain the drug to a purchaser constitutes labeling).

⁹⁶*Ramirez v. Plough*, 863 P.2d 167, 175 (Cal. 1993).

⁹⁷*Id.*, at 174 (stating [A]lthough warnings in English are expressly required, no California statute requires label or package warnings in any other language).

⁹⁸See *id.*, at 175 (stating [T]hese statutes demonstrate that the Legislature is able and willing to define the circumstances in which foreign-language communications should be mandated).

⁹⁹See *id.*, at 176 (stating [L]acking the procedure and the resources to conduct the relevant inquiries, we conclude that the

a case-by-case approach to the proper standard of care.¹⁰⁰ The Court surmised that such an unpredictable standard would result in all drug manufacturers providing foreign language warnings on drug labels.¹⁰¹ This result was dismissed as too onerous for drug manufacturers and because multilingual labels would unjustifiably raise the costs of drug production.¹⁰² Second, the Court contemplated a judicially-declared particularized standard of care. The Court determined that it lacked the necessary expertise and resources to create such a bright line rule for the over-the-counter drug industry.¹⁰³ As a result of rejecting these two standard of care theories, the Court concluded that the existing administrative standard of care would govern the case.

The Court also rejected the plaintiff's suggestion of a judicially-declared rule holding over-the-counter drug manufacturers responsible for label warnings in every language in which the product was advertised. This standard was posited by plaintiff's counsel, former California Supreme Court Justice Joseph Grodin, and supported by critics.¹⁰⁴ Grodin argued that advertising merely establishes that the drug maker should foresee its use by non-English speakers.¹⁰⁵ One critic claimed that such a standard is justified by the theory of strict products liability.¹⁰⁶ The Court noted that this approach of tying liability to advertising is common in similar circumstances, specifically a contract party who advertises in a foreign language must provide a

prudent course is to adopt for tort purposes the existing legislative and administrative standard of care on this issue).

¹⁰⁰ *Id.*, at 175.

¹⁰¹ *Id.*

¹⁰² *See id.*, at 175-176 (stating such an open-ended rule would likely compel manufacturers to package all their nonprescription drugs with inserts containing warnings in multiple foreign languages because, simply as a matter of foreseeability, it is foreseeable that eventually each nonprescription drug will be purchased by a non-English-speaking resident or foreign tourist proficient only in one of these languages. The burden of including warnings in so many different languages would be onerous, would add to the costs and environmental burdens of the packaging, and at some point might prove ineffective or even counterproductive if the warning inserts became so large and cumbersome that the user could not easily find the warning in his or her own language).

¹⁰³ *Id.*, at 176.

¹⁰⁴ *See* Scott Graham, *Grodin Argues Label Case Before Ex-Colleagues: Former Justice Asks Court to Uphold Ruling Requiring Non-English Warnings in Drug Packages*, THE RECORDER, Oct. 7, 1993, at 2.

¹⁰⁵ *Id.*

¹⁰⁶ Roger Enriquez, *I'm Warning You: Over-the-Counter Drug Manufacturers That Advertise in Spanish Should Warn in Spanish*, 4 J. GENDER RACE & JUST. 353, 364-65 (Spring 2001) (stating [R]equiring [over the counter] drug manufacturers who advertise in Spanish to warn in Spanish is perfectly consistent with the rationale behind strict products liability. . . 'the purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by manufacturers that put such products on the market rather than by injured persons who are powerless to protect themselves').

written contract or disclosure in the same language.¹⁰⁷ Nevertheless, the Court uses these similar standards as evidence that regulators have contemplated issues of language use and declined to require foreign languages for drug label warnings in any circumstances.¹⁰⁸ Not every member of the Court agreed on rejecting a link between label liability and advertising. In his concurrence, Judge Mosk differed from the majority by saying, I believe that as long as an over-the-counter drug manufacturer gives reasonable notice, by any legal means, of possible side effects in a foreign language to a non-English-literate consumer whose purchase has been induced in that language, it has met the standard of conduct California tort law demands.¹⁰⁹ However, the defendant still prevailed under Mosk's standard because the plaintiff's mother did not rely on any of the defendant's Spanish advertisements. Grodin also noted that a drawback of tying label language requirements to advertising is that such a standard could result in some manufacturers choosing not to advertise at all.¹¹⁰ The Court declined to link label language requirements to advertising.

The Court held that, under tort law, over-the-counter drug manufacturers have no duty to include foreign-language warnings on the label or in their packaging materials. The opinion deferred to the administrative drug label standard put forth by the FDA: the English only rule described earlier in this paper. The Court deferred to regulators for purposes of uniformity and clarity, to avoid adverse impacts upon the warning requirements mandated by the federal regulatory scheme, and in deference to the superior technical and procedural lawmaking resources of legislative and administrative bodies.¹¹¹ Wording of the opinion indicated that the Court hoped that the case would provoke an administrative response. The Court appealed to lawmakers by saying:

¹⁰⁷See *Ramirez v. Plough*, 863 P.2d 167, 177 (Cal. 1993).

¹⁰⁸See *id.*

¹⁰⁹*Id.*, at 179.

¹¹⁰Scott Graham, *Grodin Argues Label Case Before Ex-Colleagues: Former Justice Asks Court to Uphold Ruling Requiring Non-English Warnings in Drug Packages*, THE RECORDER, Oct. 7, 1993, at 2.

¹¹¹*Ramirez v. Plough*, 863 P.2d 167, 177 (Cal. 1993).

The feasibility and advisability of foreign-language labeling for nonprescription drugs will, no doubt, be reviewed periodically by the FDA and other concerned agencies. Indeed, we are conscious that our decision here may prompt review of this issue by the California Legislature. That is as it should be, for further study might persuade the Legislature, the FDA, or any other concerned agency to review the controlling statutes or regulations for nonprescription drugs.¹¹²

Despite this plea to regulators and lawmakers, the English only standard for over-the-counter drug labels remains unchanged almost a decade after the *Ramirez* decision.

Section 2: Implications of *Ramirez*

The *Ramirez* decision indicates that any change in the English only food and drug labeling policy must be initiated by regulators or lawmakers, not by the judicial system. *Ramirez* was only a state court decision, so there is a possibility of another state court or a federal court will decide that food or drug labels must be required in languages other than English. Nevertheless, no other state supreme court or federal court has heard such a case either before or after *Ramirez*. In addition, California was an ideal forum for the case due to its disproportionately large Spanish speaking population. A state with a less significant Spanish speaking population is unlikely to impose an opinion requiring multilingual food or drug labels.

As long as the FDA's English only standard remains static, a state regulation requiring multilingual food labels is unlikely due to preemption problems, although a state requirement of multilingual drug labels might not be preempted. The 1990 Food Labeling Amendments prohibit any state law from directly or indirectly establishing any food labeling requirement...that is not identical to FDA requirements.¹¹³ Thus, a state cannot enact a food requirement that requires multilingual labeling because the state provision would not be identical to 21 C.F.R. 101.15(c). Similarly, a state drug provision can be invalidated if there is a direct and positive conflict between FDA requirements and the state law.¹¹⁴ Thus, a state regulation cannot positively conflict with the English only labeling requirement of 21 C.F.R. 201.15(c). However, a state

¹¹³Hutt & Merrill, *supra* note 4, at 1038-39.

¹¹⁴*Id.*, at 1032.

provision requiring multilingual over-the-counter drug labels may not be prohibited because as long as the label contained the necessary information written in English, regardless information written in a foreign language, the statute does not conflict with FDA regulations. Any state requirement for multilingual drug labels would effectively cause every nation-wide drug distributor to use multilingual labels. *Ramirez* leaves open the possibility of state regulation requiring multilingual labels on drugs, but not on food.

Ramirez does not foreclose the rule-making option of linking label language requirements to advertising. An example of this type of rule is a federal regulation requiring over-the-counter drug labels to include warnings in every language in which the specific drug was advertised. The prospect of such a rule administratively daunting because drug labeling and drug advertising are regulated by two separate government agencies. The Federal Trade Commission (FTC) governs drug advertising while the FDA regulates drug labeling. Thus, any provision linking labels and advertising would necessitate administrative collaboration between the FDA and the FTC.

Although *Ramirez* seems to foreclose judicial intervention in the English only rule of food and drug labels, the case encourages regulatory reevaluation of this policy on both the state and federal level. The most practical candidates for change in this regulatory area are state laws and the FDA.

Chapter 3: A Bilingual Model - Canada

Canada employs a bilingual label system, requiring food and drug labels to include all regulated label information in both English and French. Unlike the United States, Canada has two official languages: English and French.¹¹⁵ The Canadian Food and Drugs Act regulates the labeling of Food, Drugs, and Cosmetics. Label information mandated by this Act must appear in both English and French.¹¹⁶

Canadian regulations require that most drug label information is in either French or English, however, certain information must appear in both languages.¹¹⁷ Specifically, adequate directions for use of non-prescription drugs must appear in both French and English on the label.¹¹⁸ On the other hand, any other required statement, information or declaration need only be in either French or English on the label.¹¹⁹ By only requiring that directions for use appear in both languages, the Canadian government recognizes the relative importance to the consumer of directions for use over other drug label information. In addition, the regulation indicates a concern with non-prescription drug labels as opposed to prescription drug labels. One possible rationale is that prescription products must be explained by a physician, who is presumably communicating with the patient, while non-prescription drugs have no physician intermediary so their directions for use must appear in both languages. The drug statutes also provide mandated label language in both French and English, to prevent inconsistencies in the wording and translation used by manufacturers.¹²⁰ Canadian drug regulations indicate a particular concern about the language of directions for use on non-prescription drug labels.

¹¹⁵See C.R.C., C. 870, s. B.01.012(1)(c) (2002) (stating that for the purposes of food regulations, 'official languages' means the English language and the French language).

¹¹⁶See C.R.C., C.870, s. A.01.015 (2002); See C.R.C., C. 870, s. B.01.012(2) (2002); See C.R.C., c. 869, s. 24(1) (2002).

¹¹⁷See C.R.C., C.870, s. A.01.015 (2002).

¹¹⁸*Id.* (stating adequate directions for use required to be shown on the inner and outer labels of a drug... shall be in both the French and English languages if the drug is available for sale without prescription in an open shelf-selection area).

¹¹⁹*Id.* (stating any statement, information or declaration that is required by these Regulations to appear on the label of any drug shall be in either the French or the English language in addition to any other language).

¹²⁰See, e.g., C.R.C., C. 870, s. C.01.005(1) (requiring label wording to read Drug Identification Number or Drogue: identification numerique or both).

Canadian food labels must include all required information in both English and French in most cases.¹²¹ Canadian regulations make an exception to the bilingual label requirement when an official language is the mother tongue¹²² of less than 10 percent of the population of the local government unit.¹²³ In these cases, the label information need only appear in the official language that is the mother tongue of more than 10 percent of the population of the local government unit.¹²⁴ Nevertheless, this exception is not valid if each of the official languages are the mother tongue of less than 10 percent of the population of the local government unit.¹²⁵ Thus, the language of Canadian food labels is responsive to the prominence of a language in a given local government unit. Like the drug regulations, Canadian food statutes provide required label wording in French and English to guard against inconsistencies in the terms and translations that manufacturers use on labels.¹²⁶ Canadian food labels are primarily bilingual; however, the language of the label is somewhat responsive to the prominence of the language in a given area.

Cosmetic labels require bilingual listings of certain information. An avoidable hazard presented by a cosmetic must appear on the label in both French and English.¹²⁷ Thus, Canadian regulations require that any avoidable threat appear in both languages on the cosmetic label to protect the consumer from the possible harm.¹²⁸

Canadian regulations provide a model system for implementing bilingual food and drug labels. The regu-

¹²¹See C.R.C., C. 870, s. B.01.012(2) (2002) (stating all information required by these Regulations to be shown on the label of a food shall be shown in both official languages).

¹²²C.R.C., C. 870, s. B.01.012(1)(c) (2002) (defining mother tongue as the language first learned in childhood by persons in any area of Canada and still understood by them as ascertained by the decennial census taken immediately preceding the date on which the food... is sold to the consumer).

¹²³C.R.C., C. 870, s. B.01.012(1) (2002) (defining local government unit as a city, metropolitan government area, town, village, municipality or other area of local government but does not include any local government unit situated within a bilingual district established under the Official Languages Act); See C.R.C., C. 870, s. B.01.012(3) (2002).

¹²⁴See C.R.C., C. 870, s. B.01.012(3) (2002).

¹²⁵See C.R.C., C. 870, s. B.01.012(4) (2002).

¹²⁶See, e.g., C.R.C., C. 870, s. B.01.007(1.2) (2002) (replacing required food label terms *best before* and *meilleur avant* with the terms *packaged on* and *empaqueté le*).

¹²⁷C.R.C., c. 869, s. 24(1) (2002).

¹²⁸*Cf.* C.R.C., c. 869, s. 24(2) (2002) (defining the avoidable hazard that must be listed in both official languages on the cosmetic label as a threat of injury to the health of the user of a cosmetic that can be... predicted... reasonably anticipated... and eliminated by specified limitations on the usage of the cosmetic).

lations recognize, in the case of drugs and cosmetics, that only information that can prevent harm to the consumer requires bilingual listings, for example, directions for use on over-the-counter drugs. The language use required on the label is responsive to the prominence of the language in a given area, in the case of food. Finally, the statutes provide the required wording in both French and English, in order to minimize inconsistencies of terms and translations used by manufacturers on the labels. The Canadian bilingual labeling model responds to realistic concerns about the inefficiencies of providing labeling information in more than one language.

Chapter Four: Policy Options

Numerous food and drug label policy options are available to law makers to remedy the problems posed by English only labels. The possible policy options range in their level of impact, cost, and effectiveness. This chapter explores several of the possible policy options. First, the FDA may implement expanded use of symbols on labels to communicate to foreign language speakers and illiterate consumers. Second, a foreign language disclaimer, to the effect of if you cannot read this label, have someone translate it for you, can appear on food and drug labels. Third, prescription drugs manufacturers can furnish foreign language patient package inserts for pharmacists by request, just as the FDA required in the early 1980s. Fourth, the multilingual label requirements can correlate with the languages in which the product is advertised. Fifth, states can independently regulate linguistic requirements of food and drug labels to correspond with linguistic population patterns. Finally, the FDA can implement a policy to ensure that all food and drug label information must appear in both English and Spanish. The benefits and drawbacks of these six policy options will be covered in this chapter.

Section 1: Expanded Use of Symbols on Labels

One policy option available to the FDA is to require expanded use of symbols on food and drug labels. Symbols have traditionally been used for toxic household chemicals and flammable products.¹²⁹ In addition, pictograms have been used infant formula packaging as directions for use.¹³⁰ Symbols and pictograms have the benefit of communicating to all consumers, regardless of the consumer's language or literacy. Nevertheless, symbols are limited in what they can express. The complex information on food and drug labels would be difficult to communicate through the use of symbols. For example, symbols cannot clearly convey the warnings on an average over-the-counter cold pill to a consumer:

¹²⁹See *Ramirez v. Plough*, 863 P.2d 167, 171 (Cal. 1993).

¹³⁰*Id.*

Do not exceed recommended dosage. If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor. If symptoms do not improve within 7 days, or are accompanied by fever, consult a doctor. Do not take this product if you have a heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland, or give this product to children under 12 years of age unless directed by a doctor. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. . . Do not use this product if you are now taking a prescription monoamine oxidase inhibitor.¹³¹

The directions for use on drugs would be similarly difficult to express through pictograms. In addition, food and drug ingredients cannot be conveyed to consumers through symbols. The *Ramirez* opinion noted the limitations of symbols on labels, stating although symbols and pictograms can be used effectively to warn that a substance is flammable or toxic, or to explain its preparation and use. . . it is doubtful that they are at present able to convey the more complex warning information typically required for nonprescription drugs.¹³² Expanded use of symbols would allow labels to communicate with all consumers that are limited in their English proficiency; however, this policy is not ideal for food and drug labels because only limited simple messages can be conveyed through pictograms

To overcome some of the limitations of symbols, Canada employs bilingual abbreviations. For example, Canada employs the abbreviation of Pr on a label to indicate a prescription drug.¹³³ Often, these abbreviations accurately represent phrases in both English and French.¹³⁴ Like symbols; however, abbreviations are limited in the messages that can be conveyed. In addition, because the terms being abbreviated are English words, the meaning of the abbreviation may not always be apparent to a consumer who cannot speak English.

¹³²*Ramirez v. Plough*, 863 P.2d 167, 171 (Cal. 1993).

¹³³C.R.C., C. 870, s. C.01.004(1)(b)(I) (2002).

¹³⁴*See, e.g.*, C.R.C., C. 870, s. C.01.005(1) (2002) (stating both the inner and outer label of a drug. . . shall show in a clear and legible manner the drug identification number assigned by the Director for that drug. . . preceded by the words 'Drug Identification Number' or 'Droque: identification numerique' or both, or the letters 'DIN').

Section 2: Foreign Language Disclaimer

The FDA can require food and drug labels with English information and multilingual disclaimers. For example, a food label can be entirely in English except for Spanish, Chinese, and French disclaimers that state if you cannot read this label, have someone translate it for you. The *Ramirez* opinion noted the option that over-the-counter drug labels could read [I]f you do not read English, ask someone to translate this label for you before using this product in a foreign language.¹³⁵ The *Ramirez* court was uncertain whether such a foreign language disclaimer would require the rest of the information on that label to appear in that foreign language, as well.¹³⁶ A foreign language disclaimer is likely to relieve a food or drug manufacturer from any potential liability to a foreign language speaking consumer because the disclaimer may qualify as a reasonable effort to warn the consumer.¹³⁷

Nevertheless, a foreign language disclaimer is not an effective way to communicate label information to consumers who speak a language other than English. With disclaimers, the consumer bears the responsibility of finding someone to translate the label. The disclaimer merely shifts the burden of translation from the manufacturer to the consumer. Moreover, the acquaintance that does translate the label may or may not provide an accurate translation. Thus, disclaimers do not ensure that the correct label information is conveyed to the consumer. The ubiquity of such a disclaimer on all food and drug labels may have a numbing effect on consumers. This numbing effect limits the effectiveness of the disclaimer. Foreign language disclaimers are not an ideal policy option because they do not ensure accurate translation and may have a numbing effect on consumers.

Section 3: Foreign Language Patient Package Inserts by Request

¹³⁵*Ramirez v. Plough*, 863 P.2d 167, 174 note 4 (Cal. 1993).

¹³⁶*Id.* (speculating that such a foreign language disclaimer might not violate regulation requiring a label with any representation in a foreign language to contain all required words, statements, and other information in that foreign language, as well).

¹³⁷*Cf. Id.*, at 171 (stating in most cases, courts have fixed no standard of care for tort liability more precise than that of a reasonably prudent person under like circumstances).

The FDA may require prescription drug companies to provide foreign language patient package inserts to pharmacists by request. In the early 1980s, the FDA mandated that Spanish patient package inserts be available to pharmacists upon request, as part of the larger patient package insert program. This program no longer exists. Nevertheless, the FDA could revive the foreign language provision of the patient package insert program. This policy option is efficient because the foreign language patient package inserts are likely to only be provided for communities with a significant population that speaks a foreign language. The program is justified because prescription drugs, by their very nature, are the most dangerous products regulated by the FDA. Foreign language patient package inserts accomplish the FDA goals of promoting safe and effective use of prescription drug products and reducing potential liability for manufacturers and physicians.¹³⁸

A program of foreign language patient package inserts has many drawbacks. First, such a program is unnecessary because physicians already act as an intermediary for translation during the prescription process. Second, translating and producing the patient packaging inserts presents a significant cost to manufacturers. This cost was a primary reason for the revocation of the patient package insert program in the early 1980s.¹³⁹ The FDA is conscious of the need for Federal regulations to be both necessary and cost effective.¹⁴⁰ The foreign language patient package insert program appears to be neither necessary nor cost effective.

Section 4: Label Requirements Correlated with Advertising

The FDA may require that food and drug labels contain all of the required information in every language that the product is advertised within the United States. Roger Enriquez suggests, with a broad reading of the term labels, that the FDA may already require this correlation for drugs.¹⁴¹ Enriquez theorizes that a

¹³⁸ See Prescription Drug Products: Patient Labeling Requirements, 44 Fed. Reg. 40016 (July 6, 1979).

¹³⁹ See Prescription Drug Products: Revocation of Patient Package Insert Requirements, 47 Fed. Reg. 39147 (Sept. 7, 1982).

¹⁴⁰ *Id.*

¹⁴¹ See Roger Enriquez, *I'm Warning You: Over-the-Counter Drug Manufacturers That Advertise in Spanish Should Warn in Spanish*, 4 J. GENDER RACE & JUST. 353, 360 (Spring 2001) (stating any written, printed, or graphic material used in the sale of a drug to supplement or explain the drug to a purchaser constitutes labeling. . . No court has ruled whether advertising

drug label and advertising correlation can be attained through tort law in the court system.¹⁴² On the other hand, an FDA announcement of such a correlation in the Federal Register, merely by redefining the term labels to include advertising, would be effective immediately and nationwide. The Food and Drug Act could be amended to reflect such a redefinition of the term labels, establishing a mandatory correlation between the label language and advertising language for both food and drugs. Such a system would make the cost of providing multilingual labels voluntary for manufacturers. The manufacturer could choose whether or not to advertise in a given language based on whether the manufacturer could bear the cost of multilingual label translation and production. Thus, a correlation between labeling and advertising is cost effective because only manufacturers that could afford multilingual labels would advertise in foreign languages. This system is straightforward to implement, evidenced by a similar contract theory that already exists.¹⁴³ A correlation requirement is reasonable because manufacturers can foresee, for example, Spanish speaking consumers buying the product if that product is advertised in Spanish. A policy of requiring manufacturers to provide label information in the languages in which the product is advertised is cost effective, easily implemented, and reasonable.

Nevertheless, a correlation system would not ensure that multilingual labels reached the consumers who need such labels. Joseph Grodin, a former California Supreme Court Justice, warned that correlating label requirements with advertising provides a disincentive for manufacturers to advertise in foreign languages.¹⁴⁴ If, for example, a drug manufacturer chooses not to advertise in Spanish, but Spanish speaking consumers still buy the drug, the consumers still will not be able to read the label. A correlation between advertising language and label language would not ensure multilingual labels for consumers who speak a language other

in Spanish qualifies as labeling for the purposes of the FDA. If a court did rule that advertising in Spanish is labeling, then all drugs that were advertised in Spanish would also have to have labels and packaging in Spanish).

¹⁴² *Id.*

¹⁴³ See *Ramirez v. Plough*, 863 P.2d 167, 175 (Cal. 1993) (referring to a California statutes requiring that a person who used a foreign language for an advertisement, sales presentation, contract negotiations, or similar purpose must continue to use that language in written agreements and disclosures).

¹⁴⁴ See Scott Graham, *Grodin Argues Label Case Before Ex-Colleagues: Former Justice Asks Court to Uphold Ruling Requiring Non-English Warnings in Drug Packages*, THE RECORDER, Oct. 7, 1993, at 2.

than English.

Section 5: State Regulation of Label Language

States may take it upon themselves to regulate the languages required for food and drug labels. This policy option is efficient because states can base the language requirements on the particular linguistic population pattern of the state. For example, given the large Latin populations in the states of California and Texas, these states may require that information required on food and drug labels appear in both Spanish and English. Due to the large Latin contingencies in these states, pushing such a bill through the state legislature is feasible. Meanwhile, states like Nebraska, that do not have a significant minority language, can continue to require food and drug labels in only English. Thus, state regulation allows for a localized solution to the food and drug label problem posed by language differences.

Nevertheless, state regulation is not a realistic policy option because any state regulation of food and drug labels may be preempted by the FDA and due to the inefficiencies posed by nationwide distribution of products. The FDA has the power to preempt state statutes that conflict with federal food and drug laws. State regulation of language of food labels is especially likely to be preempted because the FDA requires that state rule-making in this area be identical to federal regulations.¹⁴⁵ In today's market, many food and drug products are distributed nationwide. Varying state regulations about the languages required on food and drug labels poses difficulties to the manufacturers of these products. In effect, these manufacturers would be required to provide label information in each language that is mandated in any of the 50 states. For example, a California statute requiring bilingual Spanish and English labels would, in effect, mandate that every product distributed nationwide has bilingual Spanish and English labels. Thus, state regulations are not a localized solution to varying population trends. State laws regarding the language of food and drug labels have nationwide effects. The policy option of state regulation of label languages is less than ideal

¹⁴⁵See Hutt & Merrill, *supra* note 4, at 1038-39.

because the effects of the statutes are not localized and the laws are likely to be preempted by the FDA.

Section 6: FDA Mandate of Bilingual English/Spanish Labels

The most extensive policy option is a FDA mandate of bilingual, Spanish and English, labels for food and drugs. A requirement of bilingual Spanish/English labels responds to the statistical prominence of Spanish speakers over every other linguistic minority in the United States, as well as the rapid growth of the Spanish speaking population. This model would bear similarities to the Canadian bilingual English/French model. For purposes of cost efficiency and uniformity, the FDA would provide standardized English to Spanish translations for required label wording. This FDA assistance in translation would lower costs borne by manufacturers because they will have less to translate. In addition, standardized language translations provides uniformity among the label wording, and thus familiarity for the consumer. A bilingual label requirement allows the FDA to standardize the wording on labels, assist manufacturers in translation, and respond to the prominence of the Spanish speaking population in the United States.

Nevertheless, a bilingual label requirement is not necessarily cost effective because such a mandate is both over-inclusive and under-inclusive. A bilingual label mandate is over-inclusive because Spanish labels are provided even in states with insignificant Spanish speaking populations. The policy is costly to implement due to the fact that every manufacturer would have to translate and produce bilingual labels. Bilingual labels would consume much more of the label space, detracting from manufacturer's ability to market a product on its label. The policy option is under-inclusive because such a mandate does not help linguistic minorities other than the Spanish speakers. A bilingual, Spanish and English, label requirement would be difficult for the FDA to implement because this type of mandate is not likely to be cost efficient.¹⁴⁶

¹⁴⁶ *Cf.* Prescription Drug Products: Revocation of Patient Package Insert Requirements, 47 Fed. Reg. 39147 (Sept. 7, 1982) (revoking the patient package insert requirements because the program was, among other things, not cost effective).

Chapter 5: Policy Recommendation

The realities of contemporary society necessitate that linguistic minorities be given status before the law as linguistic minorities and not as citizens on the transitional road to the English-only mainstream.¹⁴⁷

This statement explains the FDA's need to expand beyond an English only labeling system to respect the needs of the growing linguistic minority population. The number of persons in the United States who cannot understand English but can speak another language is increasing rapidly. The Spanish speaking population dominates this growing demographic. The FDA displayed concern for this group with the Spanish segment of the patient package insert program during the early 1980s. Nevertheless, since the demise of that program, the FDA has not acted to accommodate the burgeoning Spanish speaking population. The FDA's objective of communicating food and drug product information to consumers through the use of labels is lost on this Spanish speaking group because the labels are only required in English. Thus, the significant Spanish speaking population is denied access to drug directions for use along with food and drug warnings, despite the fact that many products cater to this population through Spanish language advertising.

To remedy this inequality, the FDA can ask for comment on a system of bilingual English/Spanish labels for over-the-counter drugs and reinstate a system of multilingual patient package inserts for prescription drugs. This policy recommendation balances the elements of cost effectiveness, correlation to population patterns, feasibility to implement, and necessity.

By asking for comment on a regulation requiring bilingual English/Spanish labels on over-the-counter drugs, the FDA attempts to directly remedy the area of labels that poses the most immediate harm to the Spanish speaking population. Over-the-counter drugs, by their very nature, pose more immediate harm to consumers than food and less than prescription drugs. Nevertheless, prescription drugs utilize a physician intermediary

between the drug manufacturer and the consumer to convey warnings and directions for use. Over-the-counter drugs, on the other hand, are currently unable to convey essential information to the prominent Spanish speaking population. A Spanish speaking consumer that cannot understand English is inundated with Spanish drug advertisements, yet cannot read the directions for use nor warnings on an over-the-counter drug package. Given the prominent size of the Spanish speaking population with limited English proficiency and the imminent harm posed by over-the-counter drugs, bilingual English/Spanish labels are a necessity. This necessity justifies a requirement of bilingual labels for non-prescription drugs, despite the regulation's deficiency in cost effectiveness. A nationwide bilingual label mandate is not responsive to the Spanish speaking population's tendency to clump. As noted earlier, a majority of the Spanish speaking population resides in four states. The FDA bilingual label mandate would apply to all 50 states, an overinclusiveness that indicates inefficiency. Nevertheless, a nationwide bilingual mandate is unavoidable because most non-prescription drugs are distributed nationwide, anyway. Thus, even if the bilingual requirement is only imposed on four states, non-prescription drug manufacturers would be forced to use bilingual labels on all of their products due to the unpredictability of nationwide distribution. For lack of a better alternative, a bilingual label mandate is justified despite concerns about cost effectiveness.

To ease implementation, the bilingual label system can mirror its Canadian counterpart. The FDA can publish required label wording in both English and Spanish to reduce the amount of translation imposed on drug manufacturers, lowering costs. As in Canada, only essential label information, like warnings and directions for use, is mandated to appear in both languages. Manufacturers can voice any concerns about the implementation through comments. By following the proven Canadian bilingual model, the FDA can minimize concerns about implementation of the regulation.

A reinstatement of the foreign language segment of the patient package insert program responds to the needs of multiple linguistic minority groups, not just the Spanish speaking population. The program features

patient package inserts in foreign languages, but not English, to be made available to pharmacists by request. Unlike the bilingual nonprescription drug label regulation, this program efficiently responds to the clumping population pattern of linguistic minorities. Specifically, pharmacists can request patient package inserts based on the linguistic needs of their customers. As with the bilingual label mandate, the FDA can limit manufacturer translation costs by providing standardized translations in all prominent languages. The program avoids the cost drawbacks of its 1980s counterpart because the volume of patient package inserts will be minimal, due to using a by request system rather than mandating patient package inserts for every drug package. In addition, the program is more amenable to the concerns of physicians because the patient package inserts assist physicians with a potential weakness: communicating to a patient in a foreign language. A foreign language patient package insert program meets the needs of linguistic minorities and avoids some of the pitfalls of the 1980s patient package insert program.

A system of bilingual nonprescription drug labels combined with foreign language patient package inserts also responds to the academic discourse over language rights. This FDA policy recommendation provides a step towards recognizing the rights of linguistic minorities. The programs satisfy the concerns of one critic who says:

Applying a fluid conception of political community to the language debate does not demand that all linguistic minorities be transformed into monolingual English speakers but rather that linguistic difference be accommodated.¹⁴⁸

The policy recommendation recognizes the need for linguistic accommodation and language rights by providing accommodation in situations that would otherwise pose imminent harm to linguistic minorities.

Extensive analysis of the issues surrounding multilingual food and drug labels indicates that a policy recommendation of bilingual Spanish/English labels for over-the-counter drugs coupled with foreign language patient package inserts for prescription drugs meets the complex needs of the United States population. The FDA can implement these recommendations through the process of asking for comment, allowing the pros

and cons of these programs to be debated in a public forum. By limiting the regulations to drugs, the FDA is responding to the circumstances that pose the most imminent, avoidable harm to linguistic minorities. Instituting such significant changes in both the food and the drug industry simultaneously is not realistic given manufacturer costs and strain on the FDA staff. In the future, experience in implementing the policy recommendation in the drug realm can guide whether such measures will be taken in the food industry. A mandate of bilingual over-the-counter drug labels combined with a foreign language patient package insert program is an appropriate and proportionate FDA response to the increasing needs of linguistic minorities.